June 11, 2003

Dr. Ronald Joiner
Manager, Global Toxicology
General Electric Company-Plastics
One Plastic Avenue
Pittsfield, MA 01201

Dear Dr. Joiner:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2,4,6-Trimethylphenol posted on the ChemRTK HPV Challenge Program Web site on January 30, 2003. I commend the General Electric Company-Plastics for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that General Electric Company-Plastics advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2,4,6-Trimethylphenol

Summary of EPA Comments

The sponsor, General Electric Company-Plastics, submitted a test plan and robust summaries to EPA on December 30, 2002 for 2,4,6-Trimethylphenol (CAS No. 527-60-6). EPA posted the submission on the ChemRTK HPV Challenge Web site on January 30, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The Agency agrees with the submitter that adequate data are available for these endpoints for the purposes of the HPV Challenge program. Because the submitter plans to repeat the studies to "ensure accuracy and completeness," EPA strongly recommends that the new measurements follow OECD guidelines.

2. Environmental Fate. The data provided for photodegradation, stability in water (hydrolysis), and transport and distribution (fugacity) are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to perform biodegradation testing of this chemical. The submitter needs to address deficiencies in the photodegradation robust summary.

3. Health Effects. Adequate data are available for acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproductive/developmental toxicity screening test to address these endpoints. The submitter needs to specify the route of administration of the test substance for this test.

4. Ecological Effects. The fish and algae endpoints have been adequately addressed for the purposes of the HPV Challenge Program. The submitter needs to add SAR estimates or test data on an analogous chemical to support the limited data for the daphnia endpoint.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 2,4,6-trimethylphenol Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

The Agency agrees with the submitter that adequate data are available for these endpoints for the purposes of the HPV Challenge program. However, the submitter plans to repeat the studies to "ensure accuracy and completeness." If the submitter pursues this option, EPA strongly recommends that the measurements follow OECD guidelines.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

The data provided by the submitter for photodegradation, stability in water (hydrolysis), and fugacity are adequate for the purposes of the HPV Challenge Program.

Biodegradation. EPA agrees with the submitter's proposed biodegradation testing. The testing should follow OECD TG 301 (ready biodegradation).

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproductive/developmental toxicity screening test (OECD TG 422) to address these endpoints. The submitter needs to specify the route of administration of the test substance for this test.

Ecological Effects (fish, invertebrates, and algae).

Adequate data are available for the fish and algae endpoints for the purposes of the HPV Challenge Program.

Daphnia. The 24-hour study in daphnia is shorter than the normally required 48 hours for this test. The submitter needs to support the findings of the 24-hour study in daphnia with SAR estimates or measured data on an analogous chemical. Also, the submitter can provide a robust summary for a study by Kuehn et al., 1989, titled "Results of the Harmful Effects of Selected Water Pollutants (Anilines, Phenols, Aliphatic Compounds) to Daphnia Magna."

Specific Comments on the Robust Summaries

Environmental Fate

Photodegradation. In the photodegradation robust summary, the submitter included language not pertinent to this endpoint. The submitter needs to remove the paragraphs related to *"Biodegradation potential", "Estimation of Environmental Distributions", "Common Features of the Models"*, and *"Model Results for TMP"*. These three last sections are already covered under Section 8.1-Theoretical Distribution (fugacity calculation). The submitter needs to post its photodegradation results in a format similar to that followed under section 7.0, Stability in Water.

Theoretical distribution (fugacity calculation). The submitter needs to post its fugacity results in a format similar to that followed under section 7.0, Stability in Water.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

References

Kuehn, R., M. Pattard, K-D. Pernak, and A. Winter. 1989. Results of the Harmful Effects of Selected Water Pollutants (Anilines, Phenols, Aliphatic Compounds) to Daphnia Magna. Water Res. 23(4): 495-500.